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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,327	04/27/2000	Mathew John During	40174	1919
35928	7590	12/11/2003	EXAMINER	
GRAY CARY WARE FREDENRICH 1625 MASSACHUSETTS AVENUE, NW SUITE 300 WASHINGTON, DC 20036-2247			WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

## Office Action Summary

SM.

### Application No.

09/559,327

### Applicant(s)

DURING, MATHEW JOHN

### Examiner

Brian Whiteman

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/20/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8 and 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). Filed 10/20/03
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Final Rejection**

Claims 1-6, 8, 10-12 are pending examination.

Applicant's traversal, the amendment to claims 4, 8, 12 in paper filed on 10/20/03 are acknowledged and considered.

### ***Drawings***

The drawings were received on 10/20/03. These drawings are acceptable.

### ***Response to Arguments***

Applicant's arguments, see paper, filed 10/20/03, with respect to objection have been fully considered and are persuasive. The objection of the specification has been withdrawn because of the amendment to the specification.

Applicant's arguments, see paper, filed 10/20/03, with respect to objection have been fully considered and are persuasive. The objection of claim 8 has been withdrawn because of the amendment to claim 8.

Applicant's arguments, see paper, filed 10/20/03, with respect to 112 second paragraph rejection have been fully considered and are persuasive. The rejection of claim 12 has been withdrawn because of the amendment to claim 12.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 6, 8, and 10-11 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 10, 16, 17, 18, 31, and 36 of U.S. Patent No. 6,503,887. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Patent No. '887 are drawn to a method for delivering a protein to a gut tissue of a subject comprising orally delivering to the gut tissue an AAV vector.

Although the conflicting claims in the instant application and the claims in '887 are not identical, they are not patentably distinct from each other because each invention encompasses the same material and methods and the claims in "887 embrace a method of orally delivering a recombinant AAV vector to the gut of a subject. The difference between the claims of the instant application and '887 is that the claims in the instant application are not as descriptive as

the claims from the '887. Therefore, the claims of the instant application and '887 are obvious variants of one another.

Applicant's arguments filed 10/20/03 have been fully considered but they are not persuasive. A terminal disclaimer is required to overcome the rejection. However as noted in the interview summary filed 12/8/03, applicant's representative, Roberta Robins, indicated that the applicant cannot file a terminal disclaimer because the patent has a different assignee. The examiner has no suggestion for overcoming the rejection.

Claims 1, 2, 3, and 4 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 10, 16, 17, 18, 31, and 36 of U.S. Patent No. 6,503,887 in view of Sorscher et al. US Patent No. 5,552,311. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Patent No. '887 are drawn to a method for delivering a protein to a gut tissue of a subject comprising orally delivering to the gut tissue an AAV vector.

The difference between the claims of the instant application and the claims in '877 is that the instant application embraces using a liquid pharmaceutically acceptable carrier or a solid pharmaceutically carrier. However, Sorscher teaches that depending on the mode of administration of a gene, one skilled in the art can use a solid composition or a liquid carrier (column 8, lines 10-58). Thus, one of ordinary skill in the art would have motivated to combine the methods claimed in U.S. Patent '887 in view Sorscher to use either a liquid pharmaceutically acceptable carrier or a solid pharmaceutical composition for delivering a recombinant AAV vector comprising a gene of interest operably linked to a promoter to the gut of a subject. One of

ordinary skill in the art would have been motivated to use either pharmaceutical carrier because Sorscher teaches that the carriers are well known in the art for delivering a gene to a subject. Therefore, the claims of the instant application and patent '877 in view of Sorscher are obvious variants of one another.

Applicant's arguments filed 10/20/03 have been fully considered but they are not persuasive. A terminal disclaimer is required to overcome the rejection, however as noted in the interview summary filed 12/8/03, applicant's representative, Roberta Robins, indicated that the applicant cannot file a terminal disclaimer because the patent has a different assignee.

Claims 1 and 12 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 10, 16, 17, 18, 31, and 36 of U.S. Patent No. 6,503,887 in view of Horvath et al. (Hung. Ther. Vol. 37, pages 107-110, 1989). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Patent No. '887 are drawn to a method for delivering a protein to a gut tissue of a subject comprising orally delivering to the gut tissue an AAV vector.

The difference between the claims of the instant application and the claims in ‘877 is that the instant application embraces delivering a recombinant AAV comprising a non-AAV gene of interest comprises a  $\beta$ -galactosidase gene operatively linked to a promoter to a subject. However, Horvath teaches administering  $\beta$ -galactosidase to patients with lactose malabsorption (pages 107 and 110). Thus, one of ordinary skill in the art would have motivated to combine the teaching in the claims of U.S. Patent ‘887 taken with Horvath to deliver an AAV vector comprising a  $\beta$ -galactosidase gene operably linked to a promoter to the gut of a subject with

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lactose malabsorption. One of ordinary skill in the art would have been motivated to deliver an AAV vector comprising a  $\beta$ -galactosidase gene operably linked to a promoter to the gut of a subject with lactose malabsorption because Horvath teaches that  $\beta$ -galactosidase can be used to treat lactose malabsorption. Therefore, the claims of the instant application and patent '877 in view of Horvath are obvious variants of one another.

Applicant's arguments filed 10/20/03 have been fully considered but they are not persuasive. A terminal disclaimer is required to overcome the rejection, however as noted in the interview summary filed 12/8/03, applicant's representative, Roberta Robins, indicated that the applicant cannot file a terminal disclaimer because the patent has a different assignee.

## Conclusion

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (703) 306-3217.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D.  
PRIMARY EXAMINER